

1011

APR 22 2004

K040710



Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Vanguard™ Patella Components

Common Name: Patellar Component

Classification Name: Knee joint patellofemorotibial, cemented, polymer/metal/polymer, semi-constrained

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
AGC® LP Patellar Button - K912245 and K921182

Device Description: Features of the Vanguard™ Patella Components are as follows:

- 1", true dome shape
- Grooves on the under surface
- Single or 3-peg design
- Available with or without an x-ray wire
- ArCom polyethylene

Intended Use: The intended use of the Vanguard™ Patella Components is replacement of part of the knee joint in conjunction with a femoral and tibial component. Specifically:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus or posttraumatic deformity
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

Summary of Technologies: The overall design, materials and processing of the Vanguard™ Patella Components are similar to the predicate device.

Non-Clinical Testing: Engineering analysis demonstrated equivalence between the Vanguard™ Patella Components and the predicate devices.

Clinical Testing: None provided

All trademarks are property of Biomet, Inc.

MAILING ADDRESS
PO. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6630

FAX
574.267.8137

E-MAIL
biomer@biomet.com



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2004

Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corporation
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K040770

Trade/Device Name: Vanguard™ Patella Components

Regulation Number: 21 CFR 888.3560

Regulation Name: Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis

Regulatory Class: II

Product Code: JWH

Dated: March 24, 2004

Received: March 25, 2004

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Patricia Sandborn Beres

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
cc
Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): 040770

Device Name: Vanguard™ Patella Components

Indications For Use:

The Vanguard™ Patella is intended use is for replacement of part of the knee joint in conjunction with a femoral and tibial component. Specifically:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

Page 1 of 1

510(k) Number K040770